REMARKS

Claims 1-31 are pending in the Application. Claim 1 is an independent claim and claims 2-24 depend there from. Claim 25 is an independent claim and claims 26-31 depend there from. Applicants respectfully traverse the rejection of claims 1-31 and requests reconsideration of claims 1-31, in light of the following remarks.

Response to Arguments Section of Final Office Action

The "Response to Arguments" section of the final Office Action states that the "Applicant wishes to distinguish his processor by reciting that it is a hear [sic] aid processor, which translates to a processor capable of being used in a hearing aid device. Rather than specify the functions that are different within the claims, applicant instead continues to argue intended use." (Final Office Action, Page 3, Response to Arguments, Lines 4-7). However, the Applicant has not argued intended use. Rather, the Applicant argues that the structural differences of a hearing aid processor, compared to a cochlear implant processor or the transceiver processor associated with the wearable processor (WP) 16 in Schulman, are widely known by those with ordinary skill in the art. The April 12, 2006 Office Action stated that "[c]ochlear implants are a form of hearing aid and thus the first processor in Schulman is a hearing aid processor." (Office Action, April 12, 2006, Page 4, Lines 1-2). However, "**[a] cochlear implant is not a hearing aid**." ("Cochlear Implantation", Vanderbilt Medical Center, The Otology Group, www.mc.vanderbilt.edu/root/vumc.php?site=otology&doc=5003; "Teaching Children Who Listen With a Cochlear Implant", MED9EL Medical Electronics, Handbook for Educators, 2004, p. 40) (emphasis added). Rather, a cochlear implant is a surgically implanted electronic device that works by directly stimulating any functioning auditory nerves inside the cochlea with electrical impulses. **The speech processor of a cochlear implant converts sound into electrical pulses that are sent to electrode contacts implanted into the cochlea**.

In contrast, **hearing aid processors amplify sound and perform various speech enhancement and noise reduction algorithms**, for example. The amplified signal processed

sound is transmitted as acoustic energy to the user's ear canal. The widely known differences between hearing aid processors and cochlear implant processors are discussed in Paragraphs [0004] through [0011] on Pages 1 through 4 of Applicant's specification. Because the structural differences between hearing aid processors and cochlear implant processors are well known by those of ordinary skill in the art, the term "hearing aid processor" adequately describes the structure of the processor. Further, the fact that the "hearing aid processor" of Applicant's claim 1 is used in "a system that enhances the performance of a cochlear implant" demonstrates that the "hearing aid processor" is not defined as "a processor capable of being used in a hearing aid device" (i.e., the hearing aid processor of claim 1 is being used with a cochlear implant device, not a hearing aid device). Instead, a "hearing aid processor" is a signal processor capable of amplifying sound and performing various speech enhancement and noise reduction algorithms, for example, as is widely known by those of ordinary skill in the art.

Claim Rejections under 35 U.S.C. § 102 - Schulman

Claims 1-3, 5-10, 13-17, 20-26, and 29 stand rejected under 35 U.S.C. § 102(b) as being unpatentable by Schulman et al (US 5,531,774, hereinafter "Schulman").

With regard to the anticipation rejections, MPEP 2131 states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP 2131 also states that "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Regarding independent claim 1, the Applicant respectfully submits that Schulman fails to teach, suggest, or disclose, for example, "a first processor that processes signals picked up by the at least one signal input device and sends the preprocessed signal to a second processor, **wherein the first processor comprises a hearing aid processor**." Instead, Schulman discloses a wearable processor (WP) 16 that is adapted to receive audio signals received by the microphone

18 (Schulman, Column 4, Lines 48-49) and processes the audio signals in such away that makes the signals capable of data transmission from the data transmitter 34 to the ICS 12 (Schulman, Column 5, Lines 42-46). Basically, the wearable processor (WP) 16 in Schulman is a transceiver processor, not a hearing aid processor. Further, none of the processors disclosed in Schulman are a "hearing aid processor" (i.e., a signal processor capable of amplifying sound and performing various speech enhancement and noise reduction algorithms, for example, as is widely known by those of ordinary skill in the art). Because the Office Action has failed to show "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" as required for an anticipation rejection under MPEP 2131, the rejections under 35 U.S.C. § 102(b) cannot be maintained.

Therefore, Applicants respectfully submit that the Schulman reference fails to anticipate Applicants' claim 1, for at least the reasons given above. Claim 1 is an independent claim having dependent claims 2-24. Applicants believe that independent claim 1 is allowable. Because claims 2-24 are dependent claims of claim 1, Applicants respectfully submit that claims 2-24 are, therefore, also allowable for at least the same reasons given with respect to claim 1. Applicants therefore request that the rejection of claims 1-24 under 35 U.S.C. § 102(b) be withdrawn.

Regarding independent claim 25, the Applicant respectfully submits that Schulman fails to teach, suggest, or disclose, for example, "preprocessing the collected sounds in the first processor, **wherein the first processor comprises a hearing aid processor**." Instead, as mentioned above, Schulman discloses a wearable processor (WP) 16 that is adapted to receive audio signals received by the microphone 18 (Schulman, Column 4, Lines 48-49) and processes the audio signals in such away that makes the signals capable of data transmission from the data transmitter 34 to the ICS 12 (Schulman, Column 5, Lines 42-46). Basically, the wearable processor (WP) 16 in Schulman is a transceiver processor, not a hearing aid processor. Further, none of the processors disclosed in Schulman are a "hearing aid processor" (i.e., a signal processor capable of amplifying sound and performing various speech enhancement and noise reduction algorithms, for example, as is widely known by those of ordinary skill in the art). Because the Office Action has failed to show "each and every element as set forth in the claim is

found, either expressly or inherently described, in a single prior art reference" as required for an anticipation rejection under MPEP 2131, the rejections under 35 U.S.C. § 102(b) cannot be maintained.

Therefore, Applicants respectfully submit that the Schulman reference fails to anticipate Applicants' claim 25, for at least the reasons given above. Claim 25 is an independent claim having dependent claims 26-31. Applicants believe that independent claim 25 is allowable. Because claims 26-31 are dependent claims of claim 25, Applicants respectfully submit that claims 26-31 are, therefore, also allowable for at least the same reasons given with respect to claim 25. Applicants therefore request that the rejection of claims 25-31 under 35 U.S.C. § 102(b) be withdrawn.

Claim Rejections under 35 U.S.C. § 103

Claims 4, 11, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schulman et al (US 5,531,774) in view of Karunasiri (US 6,195,585).

Claims 12 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schulman et al (US 5,531,774) in view of Hahn et al. (US 6,212,431).

Claim 30 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Schulman et al (US 5,531,774) in view of Lindemann et al. (US 5,479,522).

Claim 31 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Schulman et al (US 5,531,774) in view of Lindemann et al. (US 5,479,522).

Regarding claims 4, 12, 11, 18, and 19, Applicants respectfully submit that claims 4, 12, 11, 18, and 19 are claims dependent on claim 1. Rejection of claim 1 was traversed by Applicants as set hereinabove, making rejection of claims 4, 12, 11, 18, and 19 moot.

Similarly, regarding claims 30 and 31, Applicants respectfully submit that claims 30 and 31 are claims dependent on claim 25. Rejection of claim 25 was traversed by Applicants as set hereinabove, making rejection of claims 30 and 31 moot.

Applicant reserves the right to argue additional reasons supporting the allowability of claims 1-31 should the need arise in the future.

CONCLUSION

Applicant respectfully submits that all of claims 1-31 are in condition for allowance, and requests that the application be passed to issue.

Should anything remain in order to place the present application in condition for allowance, the Examiner is kindly invited to contact the undersigned at the telephone number listed below.

Please charge any required fees not paid herewith or credit any overpayment to the Deposit Account of McAndrews, Held & Malloy, Ltd., Account No. 13-0017.

Respectfully submitted,

Dated: June 1, 2007

By: Philip Henry Sheridan
Reg. No. 59,918

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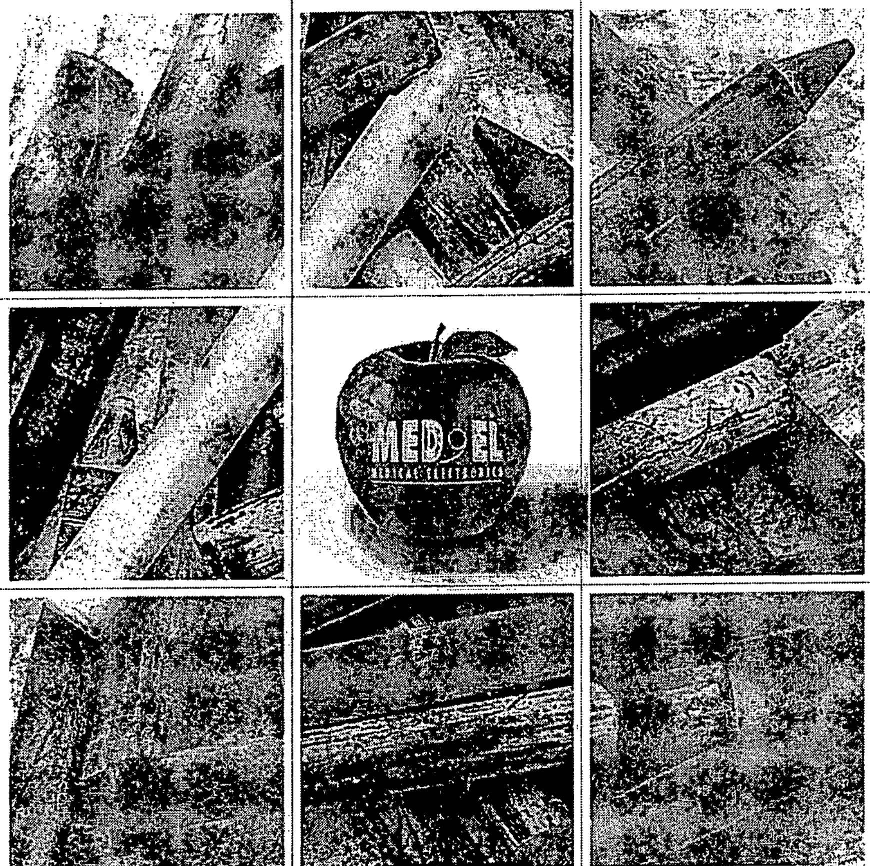
HANDBOOK FOR EDUCATORS



Teaching Children Who Listen With a Cochlear Implant

MED-EL MEDICAL ELECTRONICS

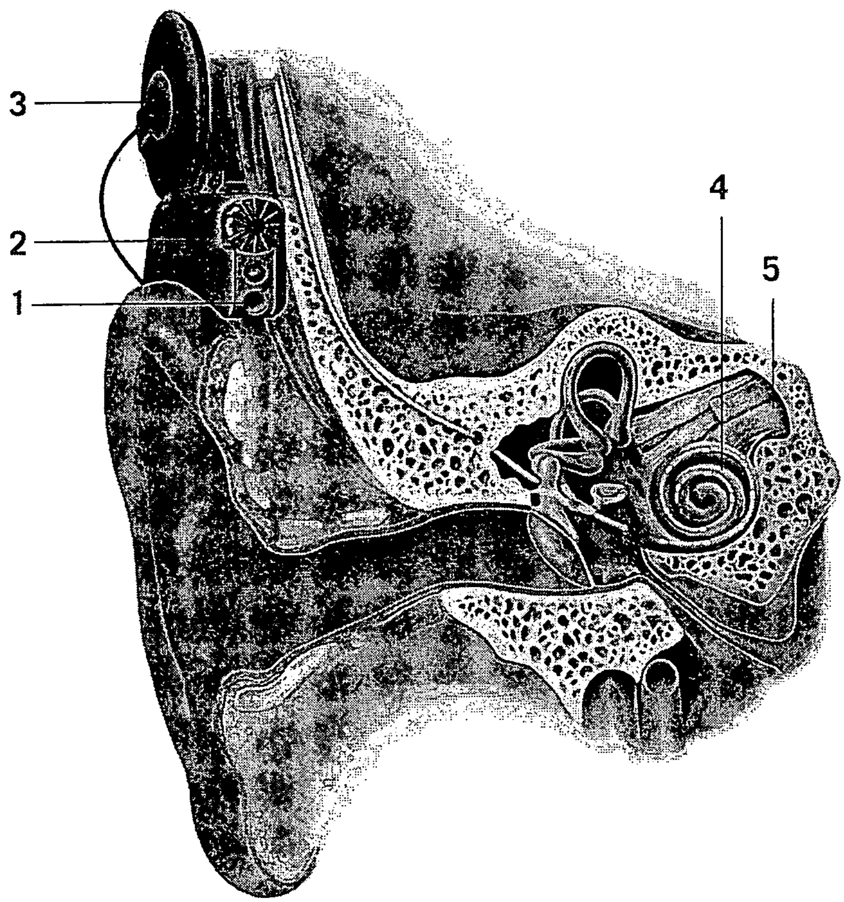
COCHLEAR IMPLANTS AND HEARING AIDS: HOW ARE THEY DIFFERENT?

A cochlear implant is not a hearing aid. Hearing aids make sound louder; they are simply miniature amplifiers that are matched to the individual's hearing loss. If the child has more hearing loss in the high pitches than in the lows, the hearing aid will be set so that high pitched sounds are amplified more than the low pitched sounds. The sound quality can be customized to some degree, and some hearing aids use digital processing to improve the quality of the sound. Hearing aids pick up sound through a microphone, amplify the sound, and present it to the ear canal. Usually the hearing aid sits in or behind the ear, and a custom-fit earmold delivers the sound to the ear canal. From there, the sound is transmitted in the normal fashion through the rest of the **outer ear**, through the **middle ear**, and into the **inner ear**. In the inner ear, the remaining nerve cells sense sound and generate tiny electrical impulses that travel along the nerve to the brain, although their ability to do this accurately may depend on the degree of hearing loss. In essence, hearing aids simply 'turn up the volume' as sound is entering the ear.

RESIDUAL HEARING OFTEN DOES NOT PROVIDE ENOUGH AUDITORY INFORMATION OR CLARITY TO ALLOW THE CHILDREN TO COMMUNICATE WITHOUT SIGNIFICANT DIFFICULTY, EVEN WITH THE USE OF HEARING AIDS.

Individuals with very extensive hearing loss often do not benefit greatly from hearing aids. They may be able to detect some (or even many) types of sounds, but those sounds may not be understandable. Some people may be able to understand speech only if they are able to see the speaker's face and get some cues from lipreading. Others may even be able to understand some speech without any visual cues. But, in the big picture of communication in daily life, their residual hearing often does not provide enough auditory information or clarity to allow them to communicate without significant difficulty, even with the use of hearing aids. These individuals are often candidates for more complex technology such as a cochlear implant.

HOW DOES A COCHLEAR IMPLANT WORK?



1 Sounds are picked up by the microphone.

2 The signal is then "coded" (turned into a special pattern of electrical pulses).

3 These pulses are sent to the coil and are then transmitted across the skin to the implant.

4 The implant sends a pattern of electrical pulses to the electrodes in the cochlea.

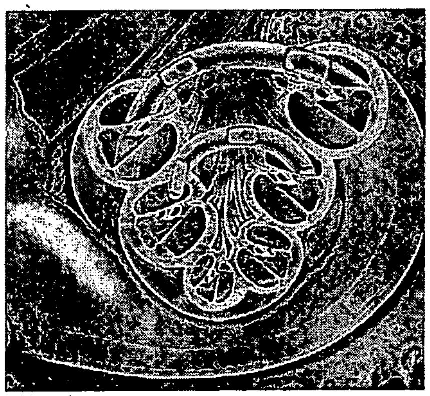
5 The auditory nerve picks up these electrical pulses and sends them to the brain. The brain recognizes these signals as sound.

Cochlear implants completely bypass the outer and middle ear. They consist of two parts – one part is surgically implanted and the other is worn outside the body. Sound is picked up by a microphone, and sent to the **speech processor**, where it goes through a complex series of circuits that code the sound into electrical impulses. This **coding strategy** is essentially doing the job of the inner ear, converting sound into electrical impulses that represent the pitch and loudness variations in sound that will be recognizable to the brain.

Once this information is properly coded, it is sent up the cable to the transmitting **coil**. The coil's job is to get this information to the implanted portion of the system. It does that by using a radio signal to send the information through the skin and into the implanted portion. The implant contains circuitry that receives and decodes this information, generates the

specified electrical pulses, and activates the **electrode contacts**, also called **channels**, that are inserted along the snail-shaped cochlea. Different electrode contacts correspond to different pitches – remember, the cochlea is tonotopically organized (see above). In the end, the electrical signals are picked up by the hearing nerve and transmitted to the brain. These signals contain the pitch and loudness information the brain needs to analyze the sound for meaning. This information is coded and sent to the hearing nerve thousands of times each second – so fast that the subtle pitch, intensity, and loudness changes of connected speech are represented accurately.

This process seems deceptively simple. However, the normal human ear contains approximately 50,000 **hair cells**, with the ability to sense a myriad of pitches, while the implant contains 12 channels that can stimulate 12 different regions along the cochlea, spanning the pitch range from low pitch to high. It is logical to think that designing an implant with 50,000 channels would do the job even better, but research tells us that cochlear implant users can understand speech best when using somewhere between 6-10 channels of stimulation. So more channels in the implant doesn't necessarily result in better understanding.

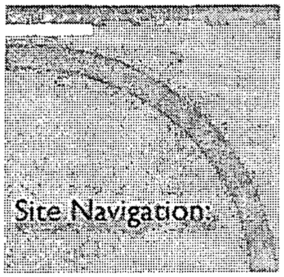


INFORMATION IS CODED AND SENT TO THE HEARING NERVE THOUSANDS OF TIMES EACH SECOND.

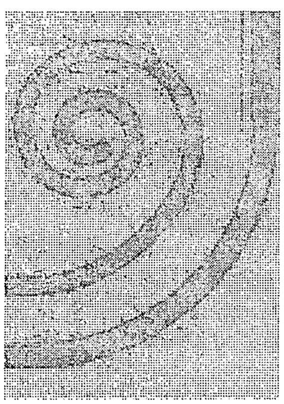
It is also important to realize that a person's brain recognizes sound by comparing it to the sounds they remember hearing over their lifetime. Adults who become deaf after a lifetime of normal hearing will have much to draw on once they regain hearing through a cochlear implant. In the case of a child who is a new cochlear implant user, his or her variety of sound experiences may be very limited. Therefore, a certain amount of learning has to take place before the child is able to attach meaning to sounds. Considering all of these factors helps to explain how such sophisticated technology provides information. However, it still takes time, patience and practice before significant improvement is noted.

WHO IS MED-EL?

The MED-EL cochlear implants represent the culmination of over 25 years of research and development in the field of cochlear implant technology. The founders of MED-EL, Drs. Ingeborg and Erwin Hochmair, are physicists who have been involved in the technical development side of cochlear implants since the 1970's, and entered the business side in 1989 when the MED-EL Company was founded in Austria. The company continues to devote approximately 35% of its revenue to further research and technology development.



- Home
- Acoustic Tumors
- Skull Base Tumors
- Implant Program
  - -Cochlear Implantation
  - -Brainstem Implantation
  - -BAHA
- Physicians
- Chronic Ear Disease
- Hearing and Balance Disorders
- Disorders of the Facial Nerve
- Brain Lab
- Temporal Bone Course
- Fellowship
- Useful Links



Cochlear Implantation

Background

The physicians at The Otology Group of Vanderbilt along with the audiologists, speech pathologists, scientists and psychologists at The Vanderbilt Bill Wilkerson Center comprise the Cochlear Implant team at the Vanderbilt Bill Wilkerson Center. The center enjoys a longstanding reputation of excellence in adult and pediatric cochlear implantation. All three manufacturer's device types are surgically implanted and programmed at the implant center and significant experience exists with each manufacturer. As one of the leading implant centers in the world, the implant center at Vanderbilt has participated in a great deal of clinical and basic science research involving cochlear implantation that promote improved performance in cochlear implant use. This research includes:

- Bilateral cochlear implantation
- New electrode design and surgical implantation
- Speech perception in noise with bilateral cochlear implantation
- Sound localization with bilateral cochlear implantation
- Distance perception in noise with bilateral cochlear implantation
- Percutaneous cochlear implantation
- Image –guided techniques in cochlear implants
- Pediatric cochlear implant trials
- Adult cochlear implant trials

What is a cochlear implant?
A cochlear implant is not a hearing aid. A cochlear implant is an electronic device manufactured and designed to assist severely to profoundly hearing impaired adults and children who gain little to no benefit from hearing aids.

How does a cochlear implant work?

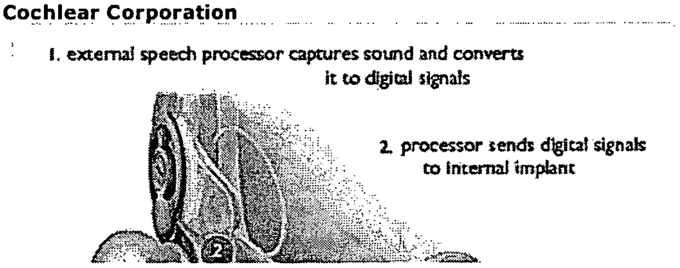
See below illustrations from all 3 of the FDA approved cochlear implant devices.

There are two main components to a cochlear implant:

1. **The receiver/stimulator** (implant) which is surgically implanted.
2. **The speech processor** (headpiece) which is not implanted and is worn externally either behind the ear (ear-level speech processor) or on the belt (body-worn processor)

- Sound is picked up by the **microphone** which a component of the externally worn speech processor
  The sound is converted in the speech processor to an electrical signal. The signal is then "coded" or converted to specific patterns or pulses.
- This coded signal is then sent to the **transmitting coil** of the speech processor where it is sent to the **receiving coil** of the internal receiver/stimulator (the implant). The signal is sent across the skin inductively, there is no direct connection with the implant: the implant in totally implanted beneath the skin.
- The implant now sends the coded electrical signal to the **electrode array** which is implanted into the cochlea.
- Multiple channels and points of stimulation now fire in a pattern that the cochlea can recognize stimulating the acoustic nerve ending in the cochlea.
- The auditory nerve pick up this signal and transmit them to the brain (auditory cortex) where they are perceived as sound

Cochlear Corporation



Basic function of the Nucleus 24 cochlear implant, Cochlear Corporation. For more information visit the manufacturer's websites listed below:

www.cochlear.com

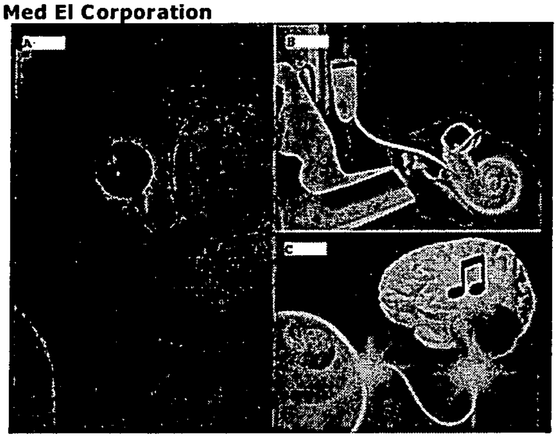
Advanced Bionics Corporation

The Advanced Bionics 90K cochlear implant. For more information visit the manufacturer's

websites listed below:

www.advancedbionics.com

Med El Corporation



Basic function of the Med El cochlear implant. For more information visit the manufacturer's websites listed below:

http://www.medel.com

A. The speech processor (headpiece) which is not implanted and is worn externally either behind the ear (ear-level speech processor) or on the belt (body-worn processor)

B. Sound is picked up by the **microphone** which a component of the externally worn speech processorThe sound is converted in the speech processor to an electrical signal. The signal is then "coded" or converted to specific patterns or pulses.

The implant now sends the coded electrical signal to the **electrode array** which is implanted into the cochlea.Multiple channels and points of stimulation now fire in a pattern that the cochlea can recognize stimulating the acoustic nerve ending in the cochlea.

C. The auditory nerve pick up this signal and transmit them to the **brain (auditory cortex)** where they are perceived as sound

Who is a candidate for a cochlear implant?

Essentially any adult or child who is severely hearing impaired who does not receive benefit from a hearing aid is a candidate for a cochlear implant. Children as young as 12 months (or younger in certain situations) can be implanted. Adults in their 80's and 90's can and have been implanted, if there are no medical reasons to not proceed with surgery.

Good candidates for the implant are as follows:

- Minimal to no benefit from the use of conventional hearing aids
- Severe to profound sensorineural hearing loss (SNHL)
- An environment at home or in school where oral communication is encouraged
- Realistic goals
- Realistic understanding of the surgery, the risks, and inherent benefits to cochlear implantation
- No significant medical issues that would make the risks of implant surgery greater than the benefit.
- For children, failure to develop good oral language skills despite intensive speech and language rehabilitation and an adequate period of hearing aid use

What are the potential benefits of cochlear implants?

The benfits of cochlear implants can vary from individual to individual depending on a variety of factors which include length of hearing loss and degree of rehabilitation following surgery. For most good candidates, the benefits are significant. Benefits may range from improved sound awareness to hearing and understanding speech in noise. Your surgeon and audiologist can discuss what would be

reasonable expectations for performance for you or your child as the level of performance depends on certain variables including length of hearing loss, motivation and available rehabilitative services among others.

- Sound awareness
- Hearing everyday sounds
- Improved lip reading
- Hearing and understanding speech
- Improving the user's own speech
- Listening in background noise
- Using a telephone

How do I determine if I am a cochlear implant candidate?

Anyone who is hearing impaired and not receiving benefit from conventional hearing aids is a potential candidate for a cochlear implant. It is wrongly assumed by some that total deafness is required prior to being a candidate for a cochlear implant. Currently, patients with residual (remaining) hearing are allowed to undergo implantation with significant improvement.

An evaluation by an audiologist experienced with cochlear implantation is necessary to determine candidacy. This evaluation is termed a candidacy evaluation and involves:

- Extensive hearing examination, with and without hearing aids
- Standardized test that determine to some degree if performance would be greater with hearing aids or with a cochlear implant (CNC words, HINT sentences)
- Speech language evaluation for communication ability and language development

Once candidacy has been established, The cochlear implant surgeon will:

Perform a complete history and physical examination

- Discuss the surgical procedure in detail
- Discuss the options to surgery
- Discuss all the risks inherent to the surgical procedure
- Discuss the device types and implant options (at our center this is also done by our implant audiology team)

In addition to this evaluation, other evaluation may be required and includes:

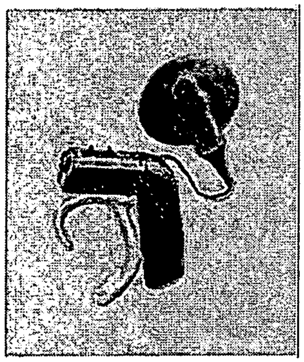
- Radiology evaluation (CT scan, MRI or both)
- Neuropsychological testing

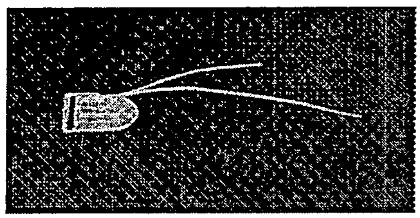
In general, the cochlear implant team will meet and discuss their evaluations and concerns prior to recommending surgery.

Cochlear Implant Device Types

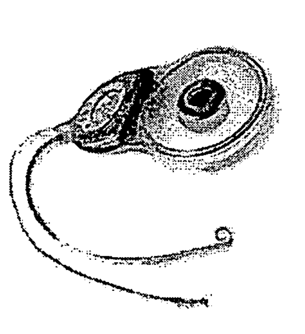
The Otology Group physicians implant cochlear implant devices from all 3 device manufacturers.

The center has experience with the surgical procedure and the rehabilitative process involved with all of the manufacturers device types. The center enjoys a strong relationship with the individual manufacturers and receives significant clinical support in programming, rehabilitative and surgical issues with the respective implants.

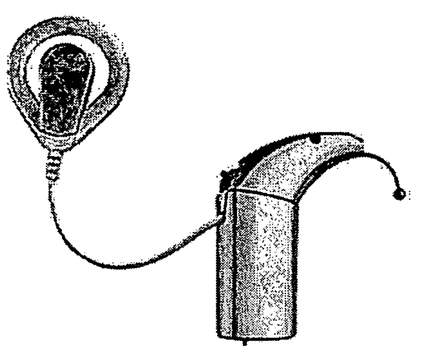




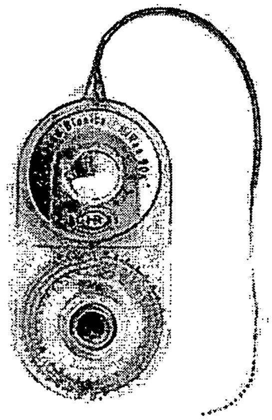
Med-El Combi-40+ Cochlear Implant



Cochlear Corporation Nucleus 24 Contour Cochlear Implant



Cochlear Corporation Speech Processor



Advanced Bionics Corporation ABC 90 K Cochlear Implant

Advanced Bionics Corporation Speech Processor

For more information visit the manufacturer's websites listed below:

http://www.medel.com

www.cochlear.com

www.advancedbionics.com

Cochlear Implant Surgical Procedure

The cochlear implant surgical procedure is done in the hospital setting under general anesthesia. The majority of the patients are able to go home on the day of surgery. The procedure usually takes from 2.5 to 3 hours.

A small incision is made in the region behind the ear. Minimally invasive techniques are employed by the physicians at The Otology Group. Minimal hair shaving is needed.

Once the incision is made the bone behind the ear is exposed anteriorly to the level of the ear canal and posteriorly to allow for insertion and securing of the implant. Removal of the aerated bone behind the ear is performed (mastoidectomy). The ear canal and ear drum are not disturbed during the procedure.

The cochlear implant is placed in its posterior position under the skin and muscle, superior and posterior to the ear and secured. A small opening is made in the cochlea (cochleostomy). The electrode is inserted into the cochlea via the cochleostomy. Full insertion is usually achieved.

The skin is closed and a dressing is applied. The dressing is removed the next day at home. The patient is seen in the clinic in 2 weeks for routine follow-up.

Follow-up and Rehabilitation

Four to six weeks after surgery the patient is scheduled to return to the clinic. At this time the external device (the speech processor) is fitted. This process is term **device activation**

and involves individual programming or **mapping** of the device by the audiologist. This programming of the processor is intensive and may take 2 to 8 visits to accomplish the best "map". This intense programming is required to achieve the maximum hearing with the implant. Experience with this process and knowledge of expected progress is essential to success. Programming time and number of visits vary depending on the patient.

Meningitis

Meningitis has been a topic of concern to many individuals interested in cochlear implants secondary to several news reports on investigations into the relationship of cochlear implants with meningitis. The results of these investigations are summarized below:

- Meningitis is an infection of the spinal fluid that surrounds thee brain and the spinal cord. The type of meningitis associated with cochlear implants is called *bacterial meningitis.*
- 90 known cases of meningitis are known worldwide. Over 60,000 cochlear implants have been implanted worldwide.
- Children with cochlear implants are more likely to get meningitis than children without cochlear implants
- Individuals undergoing cochlear implants should undergo routine vaccination for meningitis as outlined by the CDC. (see below)

Recently, the CDC and the FDA have completed an investigation that has determined that children with cochlear implants have a higher chance of getting bacterial meningitis than children without cochlear implants. Some children with hearing loss who are candidates for cochlear implants have anatomic abnormalities that put them at increased risk for meningitis whether they undergo surgery or not. The CDC has made recommendations for vaccination for meningitis that the physicians of The Otology Group of Vanderbilt follow for individuals undergoing surgery or who have existing cochlear implants. The recommendations according to the CDC include:

- Children with cochlear implants aged 2 years old or older who have completed the pneumococcal conjugate vaccine (Prevnar) series should receive one dose of the pneumococcal polysaccharide vaccine (Pneumovax 23)
- Children with cochlear implants between 24 and 59 months of age who have never received either vaccine should receive 2 doses of Prevnar 2 or more months apart and then receive one dose of Pneumovax 23 at least 2 months later.
- Persons aged 5 years or older with cochlear implants should recive one dose of pneumovax 23

For more information regarding the issues concerning meningitis and the recommended vaccination schedule contact:

www.fda.gov/cdrh/safety/cochlear.html

www.cdc.gov/nip/issues/cochlear/cochlear-gen.htm